DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 17, 2014

TSO_3 Inc.
C/O Thomas Richards, Ph.D
Consultant
IM3, Inc.
512F NE 81st Street, Suite 101
Vancouver, WA 98665

Re: K141580
Trade/Device Name: Sterizone® BI+ Self-Contained Biological Indicator, Sterizone VP4 Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 14, 2014
Received: November 17, 2014

Dear Dr. Richards,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141580

Device Name
STERIZONE® BI+ Self-contained Biological Indicator
STERIZONE® VP4 Test Pack

Indications for Use *(Describe)*

The STERIZONE® BI+ Self-contained Biological Indicator (SCBI) is intended for routine monitoring of the STERIZONE® VP4 Sterilizer, which offers a single pre-set sterilization cycle ("Cycle 1"). The SCBI should only be used in a Test Pack configuration to monitor Cycle 1. The SCBI placed within the STERIZONE® VP4 Test Pack monitors exposure to both vaporized hydrogen peroxide (H_2O_2 or VHP) and ozone (O_3) which are both used in the STERIZONE® VP4 Sterilizer. The STERIZONE® VP4 Test Pack is intended to have equivalent to greater resistance than worst case devices and loads in any load configuration.

STERIZONE® VP4 Test Pack is a device composed of the STERIZONE® BI+ Self-contained Biological Indicator (TSO_3 product code 42602, including crusher), a 10 mL syringe and its plunger, and a diffusion restrictor (sold in the form of a kit - TSO_3 product code: 44020). An external STERIZONE® CI+ Chemical Indicator (TSO_3 product code 43810) is also added to allow differentiating processed from unprocessed test packs. All components of the Test Pack are single-use, disposable items.

The STERIZONE® VP4 Test Pack is constructed by first inserting the STERIZONE® BI+ Self-contained Biological Indicator inside the syringe, with the SCBI cap facing to the Luer-lock of the syringe. The plunger is then inserted to the 10 mL mark of the syringe. The diffusion restrictor is screwed to the Luer-lock of the syringe. The chemical indicator is then inserted in the opening between the plunger and the syringe.

The test pack is placed within the load on the upper shelf of the STERIZONE® VP4 Sterilizer loading rack.

After processing, the SCBI is retrieved from the test pack. The SCBI is intended to provide users with a means to assess spore kill by the STERIZONE® VP4 Sterilizer. A "no growth" result from the SCBI after 18 hours of incubation indicates that the process achieved the conditions necessary to kill at least 1×10^6 viable spores of *Geobacillus stearothermophilus* (6 logs) on the SCBI inoculated stainless steel carrier.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

ANNEX 2

5.1. Applicant's Name and Address and submission date

Applicant's Name and Address

TSO_3 Inc.,
2505, avenue Dalton, Québec (Quebec) Canada G1P 3S5

TSO_3 Contact Person, Telephone, FAX

Marc Chaunet, Director of Regulatory Affairs
Tel : (418) 651-0003 ext.242
FAX : (418) 653-5726
E-mail : mchaunet@tso3.com

U.S. Contact

Contact: Thomas Richards, Ph.D. of IM3, Inc.
Phone: 503-415-0250
Email: tomami20x@gmail.com

Submission Date

November 13, 2014

5.2. Name of the device

Trade Name

STERIZONE® BI+ Self-contained Biological Indicator
STERIZONE® VP4 Test Pack

Common Name

Biological Indicator (Test Pack)

Classification Name (if known)

Indicator, Biological Sterilization Process

Regulatory Class

Class II under Sterilization Process Indicator in 21 CFR 880.2800 (b) by the General Hospital and Personal Use Devices Panel.
Product code: FRC

5.3. Legally Marketed Equivalent Device Name(s)

STERRAD® CYCLESURE® 24 Biological Indicator (K123017)

STERRAD® 100NX DUO Cycle Test Pack (K111391)

Verify® V24 Self-contained Biological Indicator (K090514)

5.4. Description of device

The STERIZONE® BI+ Self-contained Biological Indicator (TSO_3 product code 42602) consists of at least 10^6 *Geobacillus stearothermophilus* viable spores, known to be the reference microorganism for the STERIZONE® VP4 Sterilizer sterilization process, grouped on a stainless steel carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization. The presence of *G. stearothermophilus* spores is detected by a visual color change (media turns yellow). The yellow color change indicates bacterial growth. No change of color indicates that the process achieved the conditions necessary to kill at least 1×10^6 viable spores of *G. stearothermophilus* (6 logs) on the SCBI inoculated stainless steel carrier. The final readout of a negative result (media remains purple) is made after 18 hours of incubation when using a dry-bath type incubator.

The STERIZONE® VP4 Test Pack is a device composed of the STERIZONE® BI+ Self-contained Biological Indicator (TSO_3 product code 42602, including crusher), a 10 mL syringe and its plunger, and a diffusion restrictor (sold in the form of a kit - TSO3 product code: 44020). A STERIZONE® CI+ Chemical Indicator (TSO_3 product code 43810) is also added, external to the syringe, to allow differentiating processed from unprocessed test packs. All components of the Test Pack are single-use, disposable items.

5.5. Statement of Intended use

The STERIZONE® BI+ Self-contained Biological Indicator (SCBI) is intended for routine monitoring of the STERIZONE® VP4 Sterilizer, which offers a single pre-set sterilization cycle ("Cycle 1"). The SCBI should only be used in a Test Pack configuration to monitor Cycle 1. The SCBI placed within the STERIZONE® VP4 Test Pack monitors exposure to both vaporized hydrogen peroxide (H_2O_2 or VHP) and ozone (O_3) which are both used in the STERIZONE® VP4 Sterilizer The STERIZONE® VP4 Test Pack is intended to have equivalent to greater resistance than worst case devices and loads in any load configuration.

The STERIZONE® VP4 Test Pack is a device composed of the STERIZONE® BI+ Self-contained Biological Indicator (TSO_3 product code 42602, including crusher), a 10 mL syringe and its plunger, and a diffusion restrictor (sold in the form of a kit - TSO3 product code: 44020). A STERIZONE® CI+ Chemical Indicator (TSO_3 product code 43810) is also added, external to the syringe, to allow differentiating processed from unprocessed test packs. All components of the Test Pack are single-use, disposable items.

The STERIZONE® VP4 Test Pack is constructed by first inserting the STERIZONE® BI+ Self-contained Biological Indicator inside the syringe, with the SCBI cap facing to the Luer-lock of the syringe. The plunger is then inserted to the 10 mL mark of the syringe. The diffusion restrictor is screwed to the Luer-lock of the syringe. The chemical indicator is then inserted in the opening between the plunger and the syringe.

The test pack is then placed within the load on the upper shelf of the STERIZONE® VP4 Sterilizer loading rack.

After processing, the SCBI is retrieved from the test pack. The STERIZONE® BI+ Self-contained Biological Indicator (SCBI) is intended to provide users with a means to assess spore kill by the STERIZONE® VP4 Sterilizer. A "no growth" result from the STERIZONE® BI+ Self-contained Biological Indicator after 18 hours of incubation indicates that the process achieved the conditions necessary to kill at least 1×10^6 viable spores of *Geobacillus stearothermophilus* (6 logs) on the SCBI inoculated stainless steel carrier.

5.6. Substantial equivalence

The indicator organism, spore population and physical construction of the STERIZONE® BI+ Self-contained Biological Indicator are similar to the predicate devices for the proposed device (Table 1).

The performance characteristics and intended use of the STERIZONE® BI+ Self-contained Biological Indicator are the same as for the STERRAD® CYCLESURE® 24 Self-contained Biological Indicator (K123017) and to the Verify® V24 Self-contained Biological Indicator (K090514) (Table 1).

Table 1. Comparison between the intended use and claims for the STERIZONE® BI+ Self-contained Biological Indicator, and the STERRAD® CYCLESURE® 24 Self-contained Biological Indicator and to the Verify® V24 Self-contained Biological Indicator

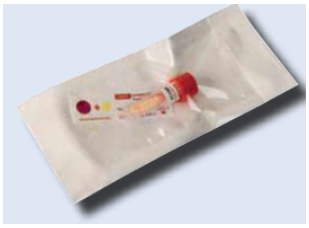
Features	STERIZONE® BI+ Self-contained Biological Indicator	STERRAD® CycleSure® 24 Biological Indicator (K123017)	Verify® V24 Self-contained Biological Indicator (K090514)
Picture of the device			
Type of BI	Self-contained BI	Self-contained BI	Self-contained BI
Organism: Spore species & Strain	*Geobacillus stearothermophilus* ATCC 7953	*Geobacillus stearothermophilus* ATCC 7953	*Geobacillus stearothermophilus* ATCC 7953
Viable spore population	Equal or greater than 1×10^6	Equal or greater than 1×10^6	Equal or greater than 1×10^6
Intended Use	Sterilization process indicator	Sterilization process indicator	Sterilization process indicator
Indications for Use	The STERIZONE® BI+ Self-contained Biological Indicator is intended to provide users with a means to assess spore kill by the STERIZONE® VP4 Sterilizer.	The STERRAD® CycleSure® Biological Indicator is intended to be used as a standard method for frequent monitoring of the STERRAD® Sterilizer cycles.	The Verify® V24 Self-contained Biological Indicator is intended to be used as a standard method for frequent monitoring of the Amsco® V-PRO™ Low Temperature Sterilization System.
Intended Use • **Method of sterilization**	STERIZONE® VP4 Sterilizer	STERRAD® Sterilization System All types of STERRAD® Sterilization Cycles, e.g: STERRAD® 100S, STERRAD® 50 STERRAD® NX™, STERRAD® 100NX™.	Amsco® V-PRO™ Low Temperature Sterilization System
• **Primary**	Hydrogen peroxide	Hydrogen peroxide	Hydrogen peroxide

Features	STERIZONE® BI+ Self-contained Biological Indicator	STERRAD® CycleSure® 24 Biological Indicator (K123017)	Verify® V24 Self-contained Biological Indicator (K090514)
sterilizing agent			
Resistance characteristics: • **D-value** • **Survival-kill window**	ΔPv_{S280} = 0.65 Torr Time = 4.3 seconds Dose = 0.39 mg/L ΔPv_{S280} = ≥ 1.28 and ≤ 11.0 Torr Time = ≥ 6.1 and ≤ 102.5 seconds Dose = ≥ 0.69 and ≤ 15.61 mg/L	Specific to the utilized resistometer and claimed sterilization system	Specific to the utilized resistometer and claimed sterilization system
Culture Conditions	Crushable "onion skin" glass containing a proprietary formulated soybean digest base with a bromocresol purple pH indicator.	Crushable glass containing a proprietary formulated soybean digest base with a pH indicator.	Crushable glass containing a proprietary formulated soybean digest base with a pH indicator.
Carrier materials	Disc made of polished **316 Stainless Steel** (non-porous carrier type)	Non-cellulosic dry spore strip made of **fiberglass**	Bottom of **polypropylene** vial
Incubation temperature	55 – 60 °C	55 – 60 °C	55 – 60 °C
Incubation time	18 hours	24 hours	24 hours
Inoculated carrier • **Primary Pack**	Capsule: Flexible polypropylene vial to hold both dry spore disc and the ampoule medium. Cap: White polypropylene cap. The cap filter is Tyvek® 1073B non-woven polyethylene	Capsule: Flexible polymeric vial to hold both dry spore strip and the ampoule medium. Cap: White polypropylene cap. The cap filter is made of non-woven polyethylene.	Capsule: Flexible polypropylene vial directly inoculated with spores and containing the ampoule medium. Cap: Orange polymeric cap. The cap filter is made of non-woven polyethylene.
Storage Conditions	15-30°C (59-86°F)	2-25°C (35-77°F) under dry conditions	21-25°C (70-77°F) 40-60 % RH
Labeling	Instructions for use Certificate of analysis	Instructions for use Certificate of analysis	Instructions for use Certificate of analysis

Features	STERIZONE® BI+ Self-contained Biological Indicator	STERRAD® CycleSure® 24 Biological Indicator (K123017)	Verify® V24 Self-contained Biological Indicator (K090514)
	Carton label Shipping label	Carton label Shipping label	Carton label Shipping label
Accessories	Activator (BI crusher)	Activator (BI crusher)	Activator (BI crusher)

Table 2 summarizes the specific device configuration for rendering each of the aforementioned biological indicators into a corresponding "test pack" or a resistant challenge to sterilization. Each version of a test pack is constructed of a biological indicator, a chemical indicator, and a diffusion restrictor intended to increase resistance. The diffusion restrictor varies from a sealed pouch (STERIS® Verify – K090514) to a vial with a cap having a defined orifice (STERRAD® 100NX DUO Cycle Test Pack – K111391). The STERIZONE® VP4 Test Pack has equivalent to greater resistance than the worst case devices and loads in any load configuration, and is designed to be more resistant than the *full* half-cycle, including exposure to hydrogen peroxide and ozone. The predicate STERRAD Test Pack is claimed to be at least as resistant to the sterilization process as the biological model developed for the DUO Cycle.

Table 2. Comparison of the STERIZONE® VP4 Test Pack with the STERRAD® 100NX DUO Cycle Test Pack and the STERIS® Verify® V24 "Test Pack"

Features	STERIZONE® VP4 Test Pack	STERRAD® 100NX DUO Cycle Test Pack (K111391)	STERIS® Verify® V24 "Test Pack" (K090514)
Product description	A STERIZONE® BI+ Self-contained BI, and a syringe with diffusion restrictor for holding the BI during the sterilization cycle, along with a process chemical indicator.	A STERRAD® CycleSure® Self-contained BI, and a STERRAD® NX® Test Vial with cap for holding the BI during the sterilization cycle.	A STERIS Verify® Self-contained BI, a Verify® chemical indicator strip, and a low-temperature sterilization pouch[1]
Picture of the device			
Indications for Use	The STERIZONE® VP4 Test Pack is used for routine monitoring of the	The STERRAD® 100NX DUO Cycle Test Pack is used for routine	The Verify® V24 Self-contained Biological Indicator is intended to be

[1] Use of a pouch can increase resistance so as to create a test pack.

Features	STERIZONE® VP4 Test Pack	STERRAD® 100NX DUO Cycle Test Pack (K111391)	STERIS® Verify® V24 "Test Pack" (K090514)
	STERIZONE® VP4 Sterilizer cycle and for the performance validation of the STERIZONE® VP4 Sterilizer system using hospital-defined loads.	monitoring of the STERRAD 100NX DUO Sterilization Cycle and is also used for the periodic testing of a STERRAD 100NX System DUO cycle, using hospital-defined loads containing devices that do not exceed claims of the cycle. The STERRAD 100NX DUO Cycle Test Pack consists of a STERRAD CYCLESURE 24 Biological Indicator, vial and cap to hold the BI.	used as a standard method for frequent monitoring of the Amsco® V-PRO™ Low Temperature Sterilization System.
Intended Use **Method of sterilization** **Sterilizing agent(s)**	STERIZONE® VP4 Sterilizer Hydrogen peroxide / ozone	STERRAD® Sterilization System Hydrogen peroxide	Amsco® V-PRO™ Low Temperature Sterilization System Hydrogen peroxide
Biological challenge	STERIZONE® BI+ Self-contained Biological Indicator – Min. 1×10^6 *Geobacillus stearothermophilus* ATCC 7953 spores	STERRAD® CycleSure® 24 Self-contained Biological Indicator – Min. 1×10^6 *Geobacillus stearothermophilus* ATCC 7953 spores	STERIS Verify® V24 Self-contained Biological Indicator - Min. 1×10^6 *Geobacillus stearothermophilus* ATCC 7953 spores
Holder	Syringe and plunger– 10 mL Becton-Dickinson (B-D) plastic syringe with Luer-lock connector and its plunger	STERRAD® NX® Test Vial 9.1 mL (0.558 in3) polyethylene vial	STERIS Low Temperature Sterilization Pouch
Diffusion restrictor	18 gauge (1.02 mm diameter), 2-inch (50.8 mm) long polytetrafluoroethylene (PTFE) cannula with Luer-lok™ attachment	Polyethylene vial cap with a single orifice of 1.4-1.55 mm diameter & 2.7 mm length (i.e., thickness of cap)	Sealed Pouch
Resistance characteristics	Demonstrated to have equivalent to greater resistance than the worst case devices and loads in any load configuration.	The Test Pack is at least as resistant to the sterilization process as the biological model developed for the DUO Cycle.	Specific to the claimed sterilization system

Features	STERIZONE® VP4 Test Pack	STERRAD® 100NX DUO Cycle Test Pack (K111391)	STERIS® Verify® V24 "Test Pack" (K090514)
	Demonstrated to be more resistant than the *full* half-cycle, including exposure to hydrogen peroxide and ozone.		

Conclusion:

The STERIZONE® BI+ Self-contained Biological Indicator and STERIZONE® VP4 Test Pack are substantially equivalent to the STERRAD® CYCLESURE® 24 Self-contained Biological Indicator (K123017), to the STERRAD® 100NX DUO Cycle Test Pack (K111391), and to the Verify® V24 Self-contained Biological Indicator (K090514) with respect to intended use, indications for use, and critical technological characteristics. Overall, the subject device and predicate devices have identical intended use, and general indications for use, although the STERIZONE® VP4 Test Pack monitors exposure to both hydrogen peroxide and ozone whereas the predicate devices monitor only exposure to hydrogen peroxide. Additionally, all devices have the same general technological characteristics, and the same operating principles. Performance testing demonstrates that the STERIZONE® BI+ Self-contained Biological Indicator and STERIZONE® VP4 Test Pack are substantially equivalent to the identified predicate devices. Minor differences in technology between the subject devices and predicates do not raise new questions of safety and effectiveness when the devices are used as labeled.

5.7. Assessment of performances data

5.7.1. Summary of nonclinical performance tests

The studies were conducted to confirm that the performance characteristics of the STERIZONE® BI+ Self-contained Biological Indicator are similar to the predicate devices (3).

Table 3. Summary of nonclinical tests performed to demonstrate Safety and Effectiveness

	Performance Requirements for Effectiveness	***Results***
1	Viable population assay	Passed Within specification
2	Growth inhibition by carrier and pack materials	Passed No inhibition induced
3	Reduced incubation time validation	Passed 18 hours using a dry-bath type incubator adjusted to 55 – 60 °C
4	Effect of sterilization process on recovery media	Passed No effect
5	Stability of biological read	Passed Stable for 7 days
6	Positive Controls	Passed Viability demonstrated
7	Stability (shelf life) evaluation	Passed Ongoing stability evaluation
8	BI validation in the STERIZONE® VP4 process	Passed
9	Test Pack performance evaluation in the STERIZONE® VP4 Sterilizer process	Passed Demonstrated to have equivalent to greater resistance than the worst case devices and loads in any load configuration Demonstrated to be more resistant than the *full* half-cycle, including exposure to hydrogen peroxide and ozone
	Performance Requirements for Safety	
1	Safe for use	Passed No safety issue

5.7.2. Overall Performance Conclusions

Performance tests demonstrate that the STERIZONE® BI+ Self-contained Biological Indicator and STERIZONE® VP4 Test Pack are substantially equivalent to the predicate devices.